

Applicant traverses through the statements made by the examiner in their office action dated March 16, 2011 and submits that the Patent Specification is properly and completely submitted. "Every application, shall describe the invention indicating the subject-matter to which the invention relates" is fully met therein. The application is submitted to the extent of full and particularly described the invention and its method by which it is to be performed. The present specification is fully disclosed with the best method of performing the invention which is known to the applicant and for which the inventor is entitled to claim the protection.

However, applicant respectfully disagrees with the statement that the "Limited amount of guidance and limited number of working examples in the specification" and needs to be re-considered.

The examiner's statement "nature of the invention", is respectfully disagreed by the applicant in the light of the specification being described the best method of performing the invention along with technical information provided therein. In this context the applicant respectfully submits to reconsider. There may be many types of skin disorders, however examiner mentioning that "skin disorders can be derived from genetic disorders" needs to be considered for re-examination of the statement. In case, all the skin disorders are of genetic disorders there can be no treatment topical applications. This statement is not correct. Skin disorders derived from genetic disorders, have also both internal and topical application treatments. Rejecting the present claims by the examiner considering that "skin disorders derived from genetic disorders" is not correct. Examiner taking the view of one reference of website leaving several other publications and patents for the treatment of skin disorders is not correct. Request the examiner or their supervisors to reconsider this statement.

The examiner's statement "state of the prior art" is respectfully disagreed by the applicant. Examiner's statement about "metabolic factors", hormonal levels, auto immune factors etc. have no relevance with the present invention of topical application for psoriasis. Respectfully submits to reconsider the statements therein.

The examiner's statement "state of the prior art", "relative skill level of those in the art", "predictability or unpredictability in the art" are the statements made therein by

the examiner, which has no relevance. It is respectfully submitted that the examiner has taken the view of administration of the drugs in the present invention. Whereas the applicant in their claims 1-15 have been cancelled, and from 16, 18-22, 24-26 and 28-30 relates to claiming of a composition for treating a skin disorder wherein the composition comprises different ingredients like vanilla extract, quaternary ammonium and a cation chloride salt in an amount of percentage mentioned in the claims. Whereas, the examiner has taken the view that the claims relating to composition as relating to administration of the drug and made several statements as above. These statements of "state of the prior art", "relative skill level of those in the art", "predictability or unpredictability in the art" needs to be reconsidered in the light of composition claims. Hence, respectfully submits to reconsider the amendments made and arguments submitted in this reply, which is in continuation to previous replies.

Respectfully submitted that the statement of "breadth of the claims", to be reconsidered in the light of composition claims.

The applicant respectfully submits revised arguments in continuation with earlier submissions for consideration.

Examiner has rejected the claims - 35 USC § 103

Claims 16, 18-26, and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over McEleney et al. (US 5680962), Durr et al. (US 5997889), McAtee et al. (US 5607980) and further in view of Knoll et al. (US 4822604) for the reasons set forth in the Office Action.

Respectfully submits that, examiner has not considered the relevance of the claims or nature of its usefulness to 125million psoriasis sufferers in the world or 7.5million psoriasis sufferers in the United States.

Kindly take a look at the following which highlights the deficiencies in the examination and rejection of the claims:

Examiner's argument is:

Applicant argues that McEleney et al. does not teach treatment for psoriasis. In response to Applicant's argument, Applicant's claim is drawn toward a treatment for skin disorder, McEleney et al. teaches ingredients for topical use to treat sunburn (column 1, lines 14-22), which is a skin disorder. Topical creams are applicable to skin, which is the situs for psoriasis.

The applicant respectfully traverses through the statement made by the examiner and submits that;

Sunburn is not a disease or disorder. It is described as:

"A sunburn is reddening of the skin that occurs after you are exposed to the sun or other ultraviolet light" as per NIH, USA.

"You know sunburn when it happens: red, painful skin that feels hot to the touch. Sunburn usually appears within a few hours after sun exposure and may take from several days to several weeks to fade." as per Mayo Clinic, USA

"Sunburn is skin damage caused by ultraviolet (UV) rays in sunlight. With too much exposure to UV light, your skin overheats and becomes red and painful, and may later peel or blister." As per NHS, UK

It is clear that sunburn is like an accident and which will happen when one expose to the sun, intense light or UV light. It cannot be considered as disease or disorder. Like we will have burns on the skin due to exposure to the flames, we will have sunburn when we expose to the sun etc. It cannot be considered as disease or disorder as mentioned by the examiner in rejections. So, argument of sunburn = skin disease = psoriasis do not hold any logical explanation.

Examiner's argument is:

McEleney et al. teaches a lotion with pH 6.5 or less (column 3, lines 11-13) for topical use (column 3, line 37)...

Knoll et al. teaches a clear therapeutic care composition having a low pH and useful in the local treatment of psoriasis of the scalp (Abstract) with 1.00%, 1.50%, 0.75% ammonium chloride (column 4, line 43) and keratolytic stabilizing agent (column 5, line 8), pH range of about 3.0-6.5 (Claim 3). A method of treating psoriasis of the scalp (Claim 7).

As for concentration of vanilla, Durr et al. teaches composition to treat psoriasis (column 1, lines 33-35) with vanilla oil up to a total of 2% by volume (column 4, lines 45-47, 55) as a cream (Abstract).

The applicant respectfully traverses through the statement made by the examiner and submits that;

Examiner is considering words like pH, Cream, skin, moisturizer, Vanilla in isolation without considering the relevance or innovative step to provide a better treatment for human suffering. For example, Durr et al teaches using of vanilla purely as fragrance (column 4, line 43-45) and they did not claim any therapeutic activity for vanilla.

If we have to accept the examiner's argument of considering only words without considering relevance, then skin cream patent issued to Thomas J.Lewis (US Patent 3,016,334 dated Jan 9, 1962) is the first one we could search issued with the words skin cream, moisturizer, water, pH 4.0-6.0 etc. Then there should not be any patent issued after Thomas J.Lewis patent having these words and which is for using on skin to moisturize.

Same way, McEleney et al. (US 5680962) teaches using low pH cream for sunburns. If it is just the words of low pH and cream makes our patent unpatentable, then how McEleney got the patent over Thomas J.Lewis or Fuller, et al. (US 6,395,269) over McEleney inspite of Fuller's patent is for sunscreen lotion with pH 6.0-7.8 ?

As argued by the examiner if Knoll et al. teaches a clear therapeutic care composition having a low pH and useful in the local treatment of psoriasis of the scalp, then how come patent having both words 'scalp psoriasis and pH 3.0 to 6.0' has been granted to Jones et al (US 7,078,058).

We request examiner to consider composition, relevance and innovative step while examining instead of going for just dictionary words like cream, lotion, water, pH etc. , as there won't be any skin application without using these words.

Respectfully submitted that the following are the major differences between the present invention and the prior art cited by the examiner:

McEleney et al. (US 5680962),

McEleney teaches about Sunscreen lotion. McEleney claims "A system for applying colorized lotion to human skin with pH indicator". Moreover, sunburn is not a skin disease or disorder, as argued by the examiner.

Cation chloride salt like ammonium chloride is being used for many other purposes and there are many patents prior to McEleney, like Bergmann (US 5,456,863 October 10, 1995) where both ammonium chloride and shampoo are mentioned in the abstract itself. Hence, it is different using ammonium chloride for therapeutic skin use or using as one of the base for some other purpose.

McEleney has used Vanilla as fragrance instead of active ingredient.

Durr et al. (US 5997889),

It was mentioned clearly in the abstract itself by Durr et al that '...essential oils from a variety of plant sources are added for a range of fragrances.' Main purpose of using vanilla by Durr et al is as fragrance and not as active ingredient with therapeutic activity.

For example Peshoff (US 7,094,431) teaches treating wound due to Psoriasis and used vanilla as flavoring agent. Here purpose of using vanilla is as flavoring agent without having any therapeutic activity.

Durr et al claims Vitamin E in the composition and it is for common skin ailments like psoriasis. Whereas, both Vitamin E and Psoriasis has been mentioned by Mantynen (US 6,107,349) and Meyer (US 5,633,284) AND they have been granted patents because their composition differs from Durr et al.

McAtee et al. (US 5607980)

Like the present invention, McAtee's also claims a composition patent and they teach cationic surfactant in their composition. Surfactants are part of any cleansing preparation for scalp or skin. If we have to go just by words like cation surfactant and ammonium chloride, then patent by Mansy (US 4,303,543 Dec 1,1981) has both cation , ammonium ion and it is for using on skin.

Most of the cleansing liquids have surfactants and surfactant is a general ingredient being used in a composition. As surfactant it has relevance when other parameters are different. In isolation surfactant alone does not have any therapeutic value.

Knoll et al. (US 4822604)

Knoll et al. teaches a clear therapeutic care composition having a low pH and useful in the local treatment of psoriasis of the scalp (Abstract) with 1.00%, 1.50%, 0.75% ammonium chloride (column 4, line 43) and keratolytic stabilizing agent (column 5, line 8), pH range of about 3.0-6.5 (Claim 3). A method of treating psoriasis of the scalp (Claim 7).

Abdullah (US 6,403,108)'s patent has all the words like keratolytic, pH between about 2.3 and about 3.7, it is for skin application, it also has quaternary ammonium compounds, still it has been granted because it has Vitamin C active ingredient which is the innovative step.

With the due respects to the examiner, we would like to bring following points which has been overlooked while examining the patent:

1. The present invention is innovative because it is a composition patent with Vanilla, ammonium chloride, potassium chloride, low pH. Examiner has fabricated rejection by picking up all the 4 key parameters from different patents and fails to show all these in one patent as active agents (as claimed in our claim # 18) for treating psoriasis.
2. **35.U.S.C.101 Inventions patentable:** Whoever invents or discovers any new and useful process, machine, manufacture, or **composition of matter**, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

New composition of matter which has novelty and better utility is patentable as per the above. Our invention has a different composition which provides solution to human suffering in an innovative way.

3. Patent examiner is failed to address that none of earlier patents which has all the active agents claimed by this invention are patented in single patent with the same relevance.

Inventor has put the genuine effort to invent a composition which provides greater relief to 7.5 million Psoriasis sufferers in the United States. Inventor has put about 8 years in invention, development, testing the product. Failing to acknowledge the invention is not only doing injustice to the inventor, it will also not providing a genuine product to the psoriasis sufferers in the United States.

I request you to reconsider the above points in the light of the above submissions.

Conclusion

Applicant has made a genuine effort to respond to each of the Examiner's objections and rejections in advancing the prosecution of this case. Applicant believes that all formal and substantive requirements for patentability have been met in the earlier arguments and amendments submitted and that this case is in condition for allowance, which action is respectfully requested.

As noted earlier, if this reply does not overcome the present rejections and results in non-allowance of all claims, applicant hereby respectfully requests a personal interview with examiner following receipt of this reply, and prior to issuance of any other office action.

Respectfully submitted,

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